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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,461	09/10/2004	Eugene De Juan	SRM0045/US	6767

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EXAMINER

CARTER, KENDRA D

ART UNIT	PAPER NUMBER
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1617

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/507,461

Applicant(s)

DE JUAN ET AL.

Examiner

Kendra D. Carter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,25-30,45 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20,25-30,45 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/6/05
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claims 1-20, 25-30, 45 and 46 are pending. Claims 21-24, 28A, and 31-44A were cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- (1) Claim 29 recites the limitation "the steroid" in line 3. There is insufficient antecedent basis for this limitation in the claim.
- (2) Claim 5 recites the limitation "wherein the disease state to be treated is selected from the group consisting of ocular neovascularization, ocular inflammation and retinal degeneration". There is insufficient antecedent basis for this limitation in the claim.
- (3) Claim 19 recites the limitation "wherein the disease state to be treated is selected from the group consisting of ocular neovascularization, ocular inflammation and retinal degeneration". There is insufficient antecedent basis for this limitation in the claim.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(1) Claims 1-4, 6, 7, 9-12, 14-18, 20, 25-30, 45, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (US 5,869,079).

Wong et al. teaches a combinations of hydrophilic and hydrophobic entities in a biodegradable implants that provide controlled, sustained drug release for an extended period of time (see abstract in its entirety; addresses claims 10, 14-16, 27 and 28). Therapeutically active hydrophobic agents, which benefit from release include, non-steroidal anti-inflammatory drugs and steroids of particular interest including cortisone, prednisolone, dexamethasone, fluorometholone (see column 2, lines 63 and 64 to column 3, lines 1-5 and column 8, example 1, lines 23-25; addresses claims 3, 4, 17, 18, 29, and 45). The formulation of implants if for use in the treatment of ocular conditions, diseases, tumors and disorders are of particular interest (see column 6, lines 27-29). Implants are introduced into the suprachoroid may deliver drugs to the choroids and the anatomically apposed retina (i.e. localizing the action of the therapeutic medium at the choroids and the retina and minimizing action at other tissues of the eye and

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forming a depot of a drug between the choroids and the retina; see column 6, lines 38-40; addresses claims 2, 6, 8, 30 and 46). Suitable sites include the posterior chamber with a sub-retinal implantation (see column 6, lines 32, 33 and 61, and 62; addresses claims 1, 7, 10, 11, 12, 14, 16, 20, 25, 26-29, 45 and 46). The implants may be administered by surgical means, injection or trocar (see column 7, lines 15 and 16; addresses claims 7 and 12). Implants may be introduced over or into an avascular region. Surgically-induced avascular regions may be produced in an eye by methods known in the art. Thus, retinal displacement is inherently taught because the implants are surgically induced by sub-retinal implantation known in the art. It may be particularly desirable to produce such an avascular region over or near the desired site of treatment, particularly where the desired site of treatment is distant from the pars plana or placement of the implant at the pars plana is not possible. Introduction of implants over an avascular region will allow for diffusion of the drug from the implant and into the inner eye and avoids diffusion of the drug into the bloodstream (i.e. localized retinal detachment; see column 6, lines 43-56; addresses claims 11, 12, and 14).

(2) Claims 1, 3-5, 7, 9-12, 14-20, 25-29 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hughes et al. (US 5,869,079).

Hughes teaches surgical techniques, grafts, method for transplanting retinal cells (see abstract in its entirety) for treatment of for use in the reconstruction of a dystrophic retina (see column 2, lines 57-59) such as retinal degeneration (see column 15,

example 2, line 37; addresses claims 5 and 19). An instrument is used to detach the retina and then the graft comprising a photoreceptor layer attached to the gelatin substrate is inserted with a tube that comprises a plunger (i.e. injection; see figure 10) into the sub-retinal space to the posterior of the eye (see column 11, lines 62-67 to column 12, lines 1-2; addresses claims 1, 3, 7, 9, 11, 12, 20, 25, 26 and 29). The gelatin serves as a carrier for a number of trophic agents including dexamethasone (see column 7, lines 5-8; addresses claims 3, 4, 17, 18, 29 and 45). Upon dissolution of the substrate, the factor or agent becomes available to impart the desired effect upon the surrounding tissue. The substrate may contain biodegradable polymers to act as slow release agents for pharmacologic substances (see column 7, lines 10-16; addresses claims 10, 14-16, and 26-28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(1) Claims 5 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (US 5,869,079) as applied to claims 1-4, 6, 7, 9-12, 14-18, 20, 25-30, 45, and 46 above in view of Hughes et al. (US 5,869,079) as applied to claims 1, 3-5, 7, 9-20, 25-29 and 45 above.

Wong et al. teachings are as applied to claims 1-4, 6, 7, 9-12, 14-18, 20, 25-30, 45, and 46 above.

Hughes et al. (US 5,869,079) teachings are as applied to claims 1, 3-5, 7, 9-20, 25-29 and 45 above.

Wong et al. does not teach a method to specifically treat the ocular diseases ocular neovascularization, ocular inflammation and retinal degeneration (claims 5 and 19).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Wong et al. and the specific ocular diseases ocular neovascularization, ocular inflammation and retinal degeneration because of the following teachings: (1) Wong et al. teaches of implants for use in the

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treatment of ocular conditions, diseases, tumors and disorders (see column 6, lines 27-29); (2) ocular neovascularization, ocular inflammation and retinal degeneration are all ocular diseases; (3) Hughes et al. teaches grafts comprising drugs such as dexamethasone for treatment of for use in the reconstruction of a dystrophic retina (see column 2, lines 57-59; column 7, lines 5-8; and see column 11, lines 62-67 to column 12, lines 1-2) such as retinal degeneration (see column 15, example 2, line 37). Thus, implants are known in the art to treat ocular diseases such as ocular neovascularization and retinal degeneration.

(2) Claims 1, 7, 8 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louis (US 5,641,750) in view of Wong et al. (US 5,869,079) in further view of Hughes et al. (US 5,869,079).

Louis teaches a method for treating injury or degeneration of retinal neurons, particularly photoreceptors, by administering glial cell line-derived neurotrophic factor, GDNF (see title and abstract, lines 1-4). The protein product may be administered intraocularly by ocular injection (see column 4, line 66 and column 5, line 15 and claim 18). Intraocular systems are those systems which are suitable for use in any tissue compartment within, between or around the tissue layers of the eye itself (see column 18, lines 39-41). A particularly suitable vehicle for intraocular injection is sterile distilled water in which the GDNF protein product is formulated as a sterile, isotonic solution, properly preserved. Yet another ophthalmic preparation may involve the formulation of

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the GDNF protein product with an agent, such as injectable microspheres or liposomes, that provides for the slow or sustained release of the protein which may then be delivered as a depot injection. Other suitable means for the intraocular introduction of GDNF protein product includes, implantable drug delivery devices or which contain the GDNF protein product (see column 19, lines 9-19).

Louis does not teach does not teach administration to the posterior segment of the eye by instilling the therapeutic medium sub-retinally between the choroids and the retina. A localized retinal detachment to define the sub-retinal space and disposing the therapeutic medium that space is in taught.

Wong et al. teaches a combinations of hydrophilic and hydrophobic entities in a biodegradable implants that provide controlled, sustained drug release for an extended period of time (see abstract in its entirety; addresses claims 10, 14-16, 27 and 28). Therapeutically active hydrophobic agents, which benefit from release include, non-steroidal anti-inflammatory drugs and steroids of particular interest including cortisone, prednisolone, dexamethasone, fluorometholone (see column 2, lines 63 and 64 to column 3, lines 1-5 and column 8, example 1, lines 23-25; addresses claims 3, 4, 17, 18, 29, and 45). The formulation of implants if for use in the treatment of ocular conditions, diseases, tumors and disorders are of particular interest (see column 6, lines 27-29). Implants are introduced into the suprachoroid may deliver drugs to the choroids and the anatomically apposed retina (i.e. localizing the action of the therapeutic medium

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at the choroids and the retina and minimizing action at other tissues of the eye and forming a depot of a drug between the choroids and the retina; see column 6, lines 38-40; addresses claims 2, 6, 8, 30 and 46). Suitable sites include the posterior chamber with a sub-retinal implantation (see column 6, lines 32, 33 and 61, and 62; addresses claims 1, 7, 10, 11, 12, 14, 16, 20, 25, 26-29, 45 and 46). The implants may be administered by surgical means (i.e. retinal displacement), injection or trocar (see column 7, lines 15 and 16; addresses claims 7 and 12). Implants may be introduced over or into an avascular region. Surgically-induced avascular regions may be produced in an eye by methods known in the art. It may be particularly desirable to produce such an avascular region over or near the desired site of treatment, particularly where the desired site of treatment is distant from the pars plana or placement of the implant at the pars plana is not possible. Introduction of implants over an avascular region will allow for diffusion of the drug from the implant and into the inner eye and avoids diffusion of the drug into the bloodstream (i.e. localized retinal detachment; see column 6, lines 43-56; addresses claims 11, 12, and 14).

Hughes teaches surgical techniques, grafts, method for transplanting retinal cells (see abstract in its entirety) for treatment of for use in the reconstruction of a dystrophic retina (see column 2, lines 57-59) such as retinal degeneration (see column 15, example 2, line 37; addresses claims 5 and 19). An instrument is used to detach the retina and then the graft comprising a photoreceptor layer attached to the gelatin substrate is inserted with a tube that comprises a plunger (i.e. injection; see figure 10)

into the sub-retinal space to the posterior of the eye (see column 11, lines 62-67 to column 12, lines 1-2; addresses claims 1, 3, 7, 9, 11, 12, 20, 25, 26 and 29).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Louis and administration to the posterior segment of the eye by instilling the therapeutic medium sub-retinally between the choroids and the retina, and further to a localized retinal detachment to define the sub-retinal space because of the following teachings: (1) Louis teaches a method for treating injury or degeneration of retinal neurons, particularly photoreceptors administered via intraocular injection, which is for use in any tissue compartment within, between or around the tissue layers of the eye itself (see column 4, line 66; column 5, line 15; claim 18; and column 18, lines 39-41); (2) Louis also teaches the method can be administered by injectable microspheres or liposomes, that provides for the slow or sustained release of the protein which may then be delivered as a depot injection, or implantable drug delivery devices which contain the GDNF protein product (see column 19, lines 9-19); and (3) Wong et al. teaches formulation of implants for use in the treatment of ocular conditions, diseases, tumors and disorders (see column 6, lines 27-29), wherein the implants are introduced into the suprachoroid to deliver drugs to the choroids and the anatomically apposed retina (i.e. localizing the action of the therapeutic medium at the choroids and the retina and minimizing action at other tissues of the eye and forming a depot of a drug between the choroids and the retina; see column 6, lines 38-40); (4) Wong et al. also teaches that suitable sites include the

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posterior chamber with a sub-retinal implantation (see column 6, lines 32, 33 and 61, and 62), wherein the implants may be administered by surgical means (i.e. localized retinal detachment), injection or trocar (see column 7, lines 15 and 16); and (5) Hughes et al. teaches an instrument that is used to detach the retina and then a graft comprising a photoreceptor layer attached to the gelatin substrate is inserted with a tube that comprises a plunger (i.e. injection; see figure 10) into the sub-retinal space to the posterior of the eye (see column 11, lines 62-67 to column 12, lines 1-2) for the treatment of as retinal degeneration (see column 15, example 2, line 37). Thus, one skilled in the art would be motivated to combine the method of Louis and the administration of the therapy to the particular region of the eye and by a localized retinal detachment because implant injections have been successfully used to treat ocular diseases and disorders in this manner as shown by Wong et al. and Hughes et al.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

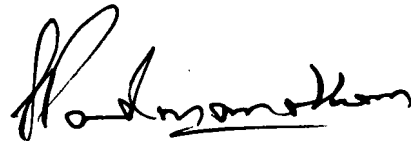
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER